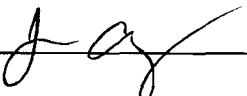
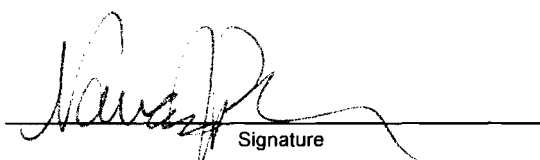


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PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional)	
		1291.1138101	
<p>I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]</p> <p>on <u>OCTOBER 20, 2010</u></p> <p>Signature <u></u></p> <p>Typed or printed name <u>JONATHON ACHEY</u></p>		Application Number	Filed
		10/658,736	SEPTEMBER 9, 2003
		First Named Inventor	
ALAN SHLUZAS		Art Unit	Examiner
3775		NICHOLAS W. WOODALL	
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p> <p>I am the</p> <p><input type="checkbox"/> applicant/inventor.</p> <p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</p> <p><input checked="" type="checkbox"/> attorney or agent of record.      40, 364 Registration number</p> <p><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34</p> <p> Signature NANCY J. PARSONS Typed or printed name 612.677.9050 Telephone number 10/20/10 Date</p> <p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.</p>			

<input type="checkbox"/> *Total of _____ forms are submitted.
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**UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Alan Shluzas et al.	Confirmation No.: 3377
Serial No.: 10/658,736	Examiner: Nicholas W. Woodall
Filing Date: September 9, 2003	Group Art Unit: 3775
Docket No.: 1291.1138101	Customer No.: 33469
Title: METHODS AND APPARATUSES FOR TREATING THE SPINE THROUGH AN ACCESS DEVICE	

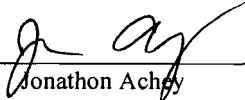
**PRE-APPEAL CONFERENCE BRIEF**

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**CERTIFICATE FOR ELECTRONIC TRANSMISSION:**

The undersigned hereby certifies that this paper or papers, as described herein, are being electronically transmitted to the U.S. Patent and Trademark Office on this 20 day of October, 2010.

By \_\_\_\_\_

  
Jonathon Achey

Dear Sir:

Applicants submit that the Examiner's rejections contain at least the following clear errors and/or omissions of one or more essential elements needed for a prima facie rejection.

Claims 20-29 were rejected under 35 U.S.C. §103(a) as being unpatentable over Puno (US 5,360,431) in view of Mathews (US 6,033,406) and Foley (US 5,792,044) and Davison (US 2001/0011170). Applicants submit this rejection is based on improper hindsight and is thus an error. The Examiner asserts that the cited Foley '044 as well as an additional Foley reference (US 6,575,899) teach performing surgical procedures in a minimally invasive manner to reduce the trauma and recovery time. The decompression (Foley '044) and fusion (Foley '988) procedures are taught as being performed through a fixed diameter cannula. One of ordinary skill in the art would understand that the procedures taught by the two Foley references involve working on a relatively small area of a single vertebra or disc, thus the procedures are understandably performed through the fixed cannulas taught by Foley. Davison teaches, "present invention is applicable to a variety of surgical procedures in which endoscopic surgical techniques are used." See paragraph [0017]. Davison also teaches, "[s]urgical instruments are

inserted into the body during endoscopic surgery through the passage 16.” See paragraph [0018]. Davison also teaches:

The expandable second tubular portion 40 of the cannula 10 provides a significantly larger working area for the surgeon inside the body 130 within the confines of the cannula. As a result, the simultaneous use of a number of endoscopic surgical instruments, including but not limited to steerable instruments, shavers, dissectors, scissors, forceps, retractors, dilators, and video cameras, is made possible by the expandable cannula 10.

See paragraph [0035]. Davison thus appears to teach using their cannula for performing endoscopic-type procedures. The two Foley references and Davison together appear to provide the suggestion, at best, for performing endoscopic-type procedures or procedures involving a relatively small area of a vertebra or disc, through a device such as that taught by Davison. Puno, however, teaches a surgical procedure involving inserting six screws and two connecting rods into both sides of three adjacent vertebrae, as clearly shown in FIGS. 17-20. Puno appears to teach an open surgical procedure for performing this two-level spinal fixation:

Initially, the area of implantation is surgically approached. A longitudinal posterior midline incision is made over the spine. The incision is carried through the subcutaneous tissue and the fascia to the tips of the spinous processes. Subperiosteal dissection is performed over the laminae and transverse processes. The facet capsule and articular cartilage are removed in preparation for fusion.

See column 6, lines 50-57. The Examiner acknowledges that Puno fails to teach inserting an access device and performing their multi-level surgical procedure through a single access device. The Examiner appears to be asserting that because the two Foley references teach the desirability of performing known surgical procedures, such as decompression and fusion, through a fixed diameter cannula, and Davison teaches performing endoscopic procedures through their expandable device, all in order to reduce trauma and recovery time, that it would have been obvious to one of ordinary skill in the art to perform the multi-level procedure of Puno through the device of Davison. Applicants respectfully disagree.

Applicants acknowledge that Foley teaches the desirability of performing decompression and fusion through a fixed cannula, and that this might show a design incentive and market forces in the art leading those skilled in the art to attempt to adapt some known surgical procedures to minimally invasive procedures. However, there is no predictability in attempting

to perform the multi-level procedure of Puno through the device of Davison. MPEP 2143.01 III states:

The mere fact that references can be combined or modified does not render the resultant combination obvious unless \*\*>the results would have been predictable to one of ordinary skill in the art. *KSR International Co. v. Teleflex Inc.*, 550 U.S. \_\_\_, \_\_\_, 82 USPQ2d 1385, 1396 (2007)

Emphasis original. The procedures of Foley and Davison appear to involve a relatively small working area, which is quite different from the three vertebrae span accessed in the procedure of Puno. Applicants submit that one of ordinary skill in the art would not expect the procedures of Foley to correlate with the procedure of Puno, thus there is no predictability in attempting to use an instrument suitable for Foley's procedures for the multi-level fixation of Puno.

The Examiner stresses that the test for combining references is what the combination of disclosures taken as a whole would suggest to one of ordinary skill in the art. Applicants do not dispute this. However, what the disclosures of the two Foley references and Davison appear to suggest is that surgical procedures such as the decompression and fusion of Foley can be performed through a cannula to reduce trauma and improve healing time, and that procedures that would generally be performed through an endoscope can be performed through the device of Davison. Adding Puno does not appear to change what the combination of references fairly suggests. Because the surgical procedure of Puno is not endoscopic and is quite different from Foley in that Puno's procedure requires accessing three vertebrae and the intervening discs at the same time, the suggestion of performing endoscopic procedures through the device of Davison does not reasonably translate to a suggestion of performing the multi-level procedure of Puno through the device of Davison. Further, the procedures of Foley are performed on a relatively small area of a single vertebra or disc, compared to the three vertebrae and two discs accessed in the procedure of Puno. One of ordinary skill in the art, upon reading the two Foley references and Davison could reasonably expect to be able to perform an endoscopic-type procedure or a relatively small area procedure such as those in Foley, through the device of Davison. However, the same cannot be said for the multi-level fixation procedure of Puno. Applicants submit the difference in size of operating field and accessibility that appears to be required for inserting six screws and two rods on opposite sides of three vertebrae for the two-level fixation procedure of Puno, as compared to the decompression and fusion procedures of Foley and endoscopic

procedures of Davison, would not lead one of ordinary skill in the art to have a reasonable expectation of success or to predict a successful outcome in attempting to perform the method of Puno through the device of Davison. The desirability of converting known surgical procedures to minimally invasive procedures does not provide any expectation of success or predictability of results. The Examiner appears to be asserting that because an outcome is desired, it would have been obvious to achieve it. KSR appears to affirm the predictability aspect of obviousness.

Puno does not teach their surgical procedure as being endoscopic, thus the skilled person would have no rational reason to look to Davison for alternative devices to using an endoscope. As discussed above, Davison appears to teach, “[s]urgical instruments are inserted into the body during endoscopic surgery through the passage 156.” See paragraph [0036]. In view of the teachings of Davison, Applicants submit that the only reason or motivation for one of ordinary skill in the art to attempt to perform the procedures of Puno through the device of Davison is found in Applicants’ specification, which is an error. The Examiner appears to be relying on Applicants’ disclosure and hindsight rather than the actual teachings of the references, in order to make a determination of obviousness. Applicants submit there is nothing in Puno to suggest or lead one of ordinary skill in the art to attempt to perform their open procedure of inserting multiple screws, rods, and cross-linking members through a device described as allowing passage of endoscopic instruments. Neither Matthews nor Foley appear to provide any rational reason or motivation for modifying Puno as asserted by the Examiner.

The Examiner further states, “examiner has provided the differences between the prior art references and the claimed invention and has provided a teaching reference with a motivation for one having ordinary skill in the art to combine the prior art teachings as required by the TSM Test (MPEP 2141).” Applicants respectfully disagree. As discussed above, Puno appears to teach an open surgical technique for inserting 6 pedicle screws, 2 rods, and one or more cross-linking members, as shown in FIGS. 14-20. Davison, however, appears to teach that, “the simultaneous use of a number of endoscopic surgical instruments, including but not limited to steerable instruments, shavers, dissectors, scissors, forceps, retractors, dilators, and video cameras, is made possible by the expandable cannula 10.” See paragraph [0035]. Davison thus appears to provide motivation, if at all, for one of ordinary skill in the art to perform an endoscopic procedure involving multiple instruments, through their device instead of an endoscope. Puno does not appear to teach an endoscopic procedure, and the Examiner has not

asserted that Puno is related to endoscopic procedures. The asserted teaching, suggestion, or motivation provided by Davison does not appear to be related to the type of procedure taught by Puno. One of ordinary skill in the art, upon reading Puno and Davison, would not have seen any teaching, suggestion, or motivation for attempting to use the device of Davison, taught as an advantage for endoscopic procedures, in the open surgical procedure of Puno. The Foley references do not appear to provide any teaching, suggestion, or motivation because, as discussed above, Foley appears to be directed to procedures involving a relatively small area of a single vertebra or disc, as opposed to the three vertebrae span involved in the procedure of Puno. Taking into account only knowledge that was within the level of ordinary skill at the time the claimed invention was made, and not including Applicants' disclosure, there is no teaching, suggestion or motivation for the skilled artisan to attempt the open surgical procedure of Puno using the device of Davison with predictable results. Applicants submit the missing part of the Examiner's argument using TSM is some teaching, suggestion, or motivation in a reference that the open surgical procedure of Puno could be performed endoscopically. The cited references fail to provide such a teaching, suggestion, or motivation. The rejection is thus an error. Reconsideration and withdrawal of the rejection are respectfully requested.

### **Conclusion**

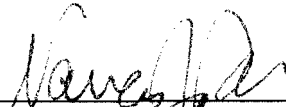
Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 767-4574.

Respectfully submitted,

Alan Shluzas et al.

By their Attorney,

Date: 10/20/10



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